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REPORT NO. 608

A METHOD FOR EVALUATING PREMEDICATION EFFICACY IN DENTAL PATIENTS

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US Army Medical Research Laboratory
Fort Knox, Kentucky

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Combat Dentistry
DA Project No. 3A012501A807
Title of Study: A Clinical Evaluation of Chloral Hydrate and Sodium Methampyrone as a Premedication for the Control of Apprehensive and Difficult Dental Patients

USAMRL Report No. 608
DA Project No. 3A012501A807

ABSTRACT

A METHOD FOR EVALUATING PREMEDICATION EFFICACY IN DENTAL PATIENTS

OBJECT

The purpose of this investigation was: first, to determine the utility of using observer ratings as a method of studying the efficacy of dental premedicating agents; and second, to test the effects of chloral hydrate and sodium methampyrone on apprehensive children.

RESULTS

The method of obtaining observer ratings from film and sound recordings of a standard dental procedure was shown to yield high inter-observer reliabilities. Both the ratings of "manageability" by dentists and of "emotionality" by psychologists were reliable and sensitive. Differences were able to be shown under double blind conditions between the first and second visit to the dental office. Contrary to expectation, a dose of 15 mg/lb body weight plus 500 mg of methampyrone had no effect on either manageability or emotionality.

CONCLUSIONS

The method was proven reliable, valid, and sensitive. Chloral hydrate and methampyrone are of no benefit as premedicating agents at the doses tested.

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A METHOD FOR EVALUATING PREMEDICATION EFFICACY IN DENTAL PATIENTS

INTRODUCTION

Fear and anxiety are common problems in a large majority of dental patients. In some patients, these conditions merely manifest themselves to a moderate degree, whereas in others, the anxiety is of such a level as to hinder dental procedures. This latter difficulty is particularly apparent in patients in the younger age groups.

There are many ways in which the dental practitioner may help his patients overcome these problems and accept the treatment more readily--through education, through reassurance, through the use of premedicating agents and, most often, with the combination of these methods. Regardless of which method or methods is used, it is of importance that the dentist have all three available in his armamentarium in order to conduct a successful and satisfying practice.

A major problem, which has occurred in choosing premedicating agents in dental practice, has been the lack of carefully controlled studies which can guarantee to the dentist that a particular agent is truly efficacious. This difficulty has arisen from two sources: first, from a tendency of most authors to report only their own subjective impressions as to the utility of the agent and not evidence from controlled studies; and second, in the difficulty of devising quantitative methods of measurement for accurately examining subjective responses, such as anxiety and fear. Recently, however, new methods have been developed which will allow for this analysis (1, 2). Using these newer methods, it has been found that subjective responses, such as the measurement of pain, tranquility, etc., and the effects of various drugs upon these subjective emotions can be quantified with a high degree of accuracy. The major purpose of the present study is the demonstration of the applicability of these methods to the study of premedicating drugs in dental practice.

A second purpose of this study is the examination of a mixture of a sedative agent, chloral hydrate, and of an analgesic, sodium methampyrone. Chloral hydrate was chosen as the sedating agent since it is among the oldest of the sedative-hypnotic group of drugs. It is one of the safest, most efficient, and least expensive of the medicinals. A pleasant taste and odor may be imparted to chloral hydrate [illegible] provided with an appropriate vehicle. It is readily absorbed [illegible]

intestinal tract, and has a wide margin of safety. Also, it produces a rapid sedation, usually within 20 minutes, which can be of particular utility in that it may be administered to the patient during the visit in which the dental operation is to be accomplished. In addition to these advantages, the drug causes no appreciable depression of blood pressure or respiration and has no depressant after effects in comparison to the barbiturates. The only major disadvantage of chloral hydrate is its irritant effects upon the gastrointestinal tract. These effects, however, can be obviated if the preparation is sufficiently dilute. It is contraindicated in the presence of renal, hepatic, or cardiac disease (3, 4, 5). It also has often been recommended for use with children (6-9).

The analgesic chosen for this study was sodium methampyrone (10) (dipyrone sodium, pyralgin), a derivative of aminopyrine. It was selected since it has been shown to provide rapid and effective pain relief in small doses and is liquid soluble.

Since the primary purpose of this study was a methodological examination, rather than an attempt to study a specific drug compound, it was deemed best by the investigators to combine both a sedative and analgesic to maximize the potential effectiveness of the compound. Thus, the essence of this investigation is the examination of the effect of a mixture of chloral hydrate and sodium methampyrone upon the manageability and the emotionality of young dental patients, who were specifically known to be difficult to handle in dental procedures.

METHOD

Subjects. From the normal flow of patients seen at the Dependents' Dental Clinic, Fort Knox, Kentucky, 75 patients were chosen for this study. They were chosen on the basis of the following criteria: one, between the age of 3 and 8 years; two, a negative health history with regard to cardiac, renal and hepatic disfunction, allergies, or coincidental drug administration; three, no overt mental deficiencies or mental disturbances; four, they appeared to be apprehensive and/or difficult to manage during treatment.

All such patients were referred to the study by dental officers who had rendered treatment. The candidates for the study were interviewed by an examining doctor, at which time a detailed health history was obtained. The patient was then given an appointment for an operative dental procedure, with the participating clinician on the project. All patients received treatment by the same dentist who had had no previous contact with them. No attempt was made to control for the sex of the subjects

Apparatus. Treatment for the study was accomplished in a dental operatory prepared with a framed glass picture window. Behind this was concealed a 16 mm motion picture camera and a tape recorder which was synchronized with the camera. A microphone was inconspicuously attached to the dental unit.

In all cases, the recording was initiated when the patient entered the room, continued through the administration of the anesthetic and then was stopped until the commencement of the operative procedure. The film was again stopped when the dentist had completed the operative procedure. Thus, the film sequence covered the same aspects of the dental treatment in both visits. In some cases, however, this was modified since the patients were unable to be anesthetized. In these cases, the filming of the operative procedure was not made.

The compounds used in this study were a placebo composed of fruit flavored syrups, and chloral hydrate and methampyrone in vehicles composed of flavored syrups. In the case of the drug group, the methampyrone and the chloral hydrate were in separate bottles, although both were mixed in syrups. The placebos were also given to the patient from two separate bottles.

The doses of the drugs given to the patient were 15 mg/lb body weight of chloral hydrate and a standard (10) 500 mg dose of sodium methampyrone. In the case of 10 subjects, a dose of only 12 mg/lb of chloral hydrate was administered. This occurred due to an error by the pharmacist compounding the drug. However, statistical analysis of the results for the 15 mg/lb of chloral hydrate and the 12 mg/lb indicate no differences between the doses. Thus, all the data were pooled together and treated as if only one dose had been administered.

This particular dose of chloral hydrate was chosen upon the basis of previous work, which has shown it to be an effective sedative dose. Goodman and Gilman (3) recommended between 6 and 12 mg/lb of chloral hydrate as the usual sedative dose for the adult. The Physicians Desk Reference (11) lists a sedative dose of chloral hydrate for children by the oral route as 5 to 10 mg/lb body weight. Thus, the dose used in this study of chloral hydrate alone, not including the fact that sodium methampyrone was added to it, is well above what might be regarded as an effective dose.

Procedure. The total treatment procedure consisted of infiltration anesthesia with 2% lidocaine hydrochloride, an occlusal cavity preparation on an upper deciduous molar, and the placement of a silver amalgam restoration, or zinc oxide and eugenol temporary.

At the conclusion of the first treatment visit, the patient was given another appointment for an operative procedure with the same doctor, at approximately the same time of day as his first appointment. The child's parent was given two bottles of medicine. In the case of the drug group, one bottle contained chloral hydrate and the other bottle contained sodium methampyrone. In the placebo group, both bottles contained the fruit flavored syrup. Which particular combination of drugs was received by any patient was unknown to the clinician or to any of the observers until the conclusion of the study.

In all cases the medication, whether placebo or drug, was administered by the parent 30 minutes prior to the second operative session. The parents were informed that it was wise to feed the child approximately 30 minutes prior to the administration of the medication in order to prevent possible gastric irritation. The drug code information was known only to the pharmacist compounding the drug and by another dentist located in the same clinic; the latter was prepared to break the code in order to treat any untoward reactions. At the second treatment visit, the same operative procedures were repeated as during the first appointment; and again, audio and visual recordings were made.

The films and recordings of these procedures were edited and then, at a later date, viewed by a panel consisting of three psychologists, the clinician who performed the operative procedures, and two other dentists. Ratings were made on a manageability scale by the dentists and on an emotionality scale by the psychologists. The ratings were made upon a six point scale; varying from one, in which the patient was described as either completely emotional or completely unmanageable; to a value of six, in which case the patient would be completely unemotional or completely manageable. A six point rating scale was used, since it has been proven in past studies that a six category scale can be effectively used for the accurate estimation of subjective impressions (12). The films had been edited so that the raters had no knowledge of whether the patient was on his first or his second visit, or whether the patient had received either the placebo or drug. This statement must be modified to a degree since, in some cases, either through statements by the clinician or by the patient in the film, the raters could determine if it was the first or the second visit. However, in no case was there any possibility of the raters knowing whether the patient had received the drug or the placebo. Thus, the study is truly double blind.

RESULTS AND DISCUSSION

The data were first analyzed using contingency coefficients to determine the inter-rater reliabilities of the observations. Since the basic

purpose of this study was to determine the efficiency of the method for analysing drugs in general, this was one of the most crucial aspects in the study. Unless it could be shown that the various observers rated the films on the same criteria, further analysis of data would be unnecessary. The Pearson "r"s between the various observers, which were estimated from the contingency coefficients, are as follows: for the emotionality ratings by the psychologists: "r" = .86, .78, and .86; for the observations of manageability made by the dentists, "r" = .94, .94, and .93 (13). It can be seen from these estimated correlation coefficients, that both the judgments of emotionality and of manageability had high and significant reliability. Thus, we may say, that although the ratings of the observers were completely independent, a high degree of agreement does exist in making these judgments. Therefore, we may state that the filming procedure that was used is adequate to lead to a high degree of inter-judge reliability.

Having established the reliability between the observers, a Pearson product moment "r" was calculated between emotionality and manageability, without regard to drug treatment or first and second visit. For this, "r" = .69. Thus, approximately 47% of the variance in manageability could be explained by emotionality, or vice versa. Approximately 50% of the variance could not be accounted for of one in terms of the other. It seems that though emotionality and manageability are related there are some aspects of difference. We might speculate that whereas manageability is strictly judged in terms of the degree of accomplishment of certain operative procedure by the dentist, in the case of the emotionality, the psychologists were judging subtler variables such as tension in the body, breathing rate, etc. It may be that in states of excessive tension and emotionality, a subject may be quite easily handled by the dentist; one might draw an analogy to a catatonic schizophrenic. Such a patient, although highly emotional, would still be placid and easily managed in the dental chair.

Since the inter-observer reliability was high, comparisons of the first and second visit, and also of the placebo vs drug effects, were based upon score totals for manageability and the emotionality categories. The scores were, therefore, free to vary between 3 and 36. It was deemed appropriate to use "t" scores rather than non-parametric statistics. The mean difference score for emotionality between the first and second visit was 1.15. The "t" score for emotionality changes between the first and second visit is 2.50; this is significant with $p < .01$. The mean difference score for manageability between the first and second visit was 0.25. The "t" score for manageability was 0.60, which is non-significant at $p < .05$.

From these data, we see that regardless of drug condition, the patients tended to be less emotional on the second visit than they were on the first. On the other hand, they did not tend to be more manageable on the second visit than they were on the first. This difference in the degree of change between the first and second visit for emotionality and manageability leads to some interesting speculations. First, we would guess that the lack of the novelty in the experience on the second visit of itself might tend to reduce the emotionality; whereas, the unpleasantness of the operation, having not been changed, might still lead the patient to be relatively unmanageable. A second speculation might be that the change in the emotionality is a direct result of the unmanageability of the patient. In this case, the lower emotionality on the second visit is due to the child learning that by being unmanageable, he can control the situation to a great degree. Certainly these speculations must be regarded as tentative, but they offer interesting possibilities for future research.

Finally, the groups were analyzed to determine the degree of change between the first and second visits for the group receiving the placebo and the group receiving the drug. That the particular procedure used in this investigation is extremely sensitive to drug differences, is shown by the fact that for the emotionality scores a mean difference of as little as .90 and for manageability of .91 would have yielded significant drug effects at $p < .05$. Thus, if on the average, the patients would have changed as little as one score category on the six point scale between drug and placebo conditions, we would have shown a drug effect at a significant statistical level. The mean change on the emotionality scale for the drug is 1.05. The mean change for the placebo group is 1.25. Therefore, the difference between the drug and placebo group means is .20. Since it would have required a mean difference of .90 to achieve significance and we have only found a difference of .20, this must be interpreted as a non-significant effect.

For the manageability scale, the mean difference for the drug group between the first and second sessions is 0.22 and for the placebo group, 0.28. Thus, the difference between the placebo and the drug for the change between the first and second session is 0.06. Since it was required to have a difference of at least .91, we again see that the difference cannot be regarded as significant. For that matter, in both cases, the direction of the change toward unemotionality or manageability is greater in the placebo group than in the drug group.

The analysis of these data show the drug to have no effectiveness in either increasing manageability or reducing emotionality. This particular result was a surprise to the investigators since we had chosen

dosages of the drugs, both sodium methampyrone and chloral hydrate, which from references to the literature, would have been expected to yield positive results. Our only possible interpretation of this data is that in the present study, in which a carefully controlled, double blind procedure was used, the failure to find drug effects must be considered as a failure of drug action. We, therefore, must wonder as to the relevance of the evidence previously reported by other investigators who have not used as rigorous a methodology.

On the whole, the authors regard this study as having accomplished, for the most part, the aims for which it was designed. We have demonstrated, that by using a carefully controlled, double blind procedure, in which films and recordings are made of patients undergoing a dental operation, independent observers will make judgments in regard to the manageability and the emotionality of the patients which are highly reliable and closely in agreement. We have also found that a degree of relationship exists between emotionality and manageability. We have found that changes take place in emotionality between the first and the second visit of these patients to the dentist; whereas, changes do not take place in the degree of manageability of the patients. And finally, we have found that at the doses tested in this study, the mixture of chloral hydrate and sodium methanipyrone is not an effective premedication for improvement of the emotional status or the manageability of children who are known to be difficult patients.

SUMMARY

The present investigation is a methodological approach to determine the efficacy of premedication with sedative and analgesic drugs in dental operative procedures. The study was carried out on young dental patients known to be difficult to handle during such dental treatment. Each patient underwent a standard dental operative procedure on two occasions; the first time without drug and the second time either with a placebo or with a mixture of chloral hydrate and sodium methampyrone. During both visits, a standard set of film and sound recordings were taken. These sound and film recordings were later rated by three dentists as to the manageability of the patient and by three psychologists as to the emotionality of the patient on a six point scale. It was found that a high degree of agreement existed between the observers on both the emotionality and the manageability scales, with all "r" values ranging between .78 and .94. It also was found that an "r" of .69 existed between the emotionality and the manageability ratings. The "t" scores showed that a significant reduction in emotionality took place between the first and second visit without regard to drug effect. However, no similar

reduction took place in the difficulty of managing the patients. Finally, it was shown that the administration of 15 mg/lb body weight of chloral hydrate and of 500 mg of sodium methampyrone had no efficacy in either reducing the emotionality of the patients or making them more manageable.

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